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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,978	09/12/2000	Roger Hull	620-106	6992

7590 07/01/2003

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

18

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,978

Applicant(s)

HULL ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☐ Claim(s) 1,3 and 6-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2003, has been entered.

Claims 1 and 3 are amended, per the amendment of 27 February 2003.

Claim 4 is cancelled.

Claims 1-3 and 6-19 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1, 3 and 6-19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the 5' region of an isolated polynucleotide consisting of SEQ ID NO:2 as an operably linked promoter for transcription of heterologous genes with said promoter, does not reasonably provide enablement for claims broadly drawn to other promoter sequences as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed November 19, 2002.

Applicant's arguments filed February 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that there is no de facto bar on the patentability of sequences that are highly homologous as a consequence of close phylogenetic relationship or highly stringent hybridization conditions, and points to specific patents that include claims that recite generic nucleotide or peptide sequences that were considered enabled (reply pages 4-5).

Applicant also argues that it would not require undue experimentation by one skilled in the art to test a sequence for promoter function, as those of skill in the art could routinely perform such assays at the time of Applicant's invention. Applicant also points out that the specification provides guidance for the performance of such assays (reply pages 5-6).

Applicant additionally argues that because the performance of such assays is routine, one skilled in the art would have no reason to select a functional sequence before performing such assays. Applicant further argues that predicting which sequences would have promoter activity is trivial, as the claims are limited to polynucleotides of promoter sequences from BSV isolates, which contribute to the definition of the genus of polynucleotides covered by the claims. Applicant also points out that in some cases the features of source and activity alone may define allowable subject matter (reply pages 6-8).

The Examiner does not dispute that there is no de facto bar on the patentability of sequences that are highly homologous as a consequence of close phylogenetic relationship or highly stringent hybridization conditions, but the Examiner maintains that the instant specification does not provide sufficient guidance for one skilled in the art to make and use such

Art Unit: 1638

sequences without undue experimentation, as only a single functional promoter sequence is exemplified.

The Examiner also does not dispute that one of skill in the art could routinely perform assays to test for promoter function at the time of Applicant's invention. The Examiner maintains, however, that it would require undue experimentation to select from among the many sequences claimed those polynucleotides that would be likely to have promoter function if subjected to a test for promoter function. With respect to the patentability of the claimed sequences, the issue is not whether one skilled in the art would have a reason to select a functional sequence before performing such an assay, the issue is whether the specification provides one of skill in the art sufficient guidance to select a functional sequence before performing such an assay.

With respect to the limitation of the claims to polynucleotides of promoter sequences from BSV isolates, the Examiner maintains that reciting a promoter function and a BSV source does not provide sufficient guidance for one skilled in the art to make and use the claimed sequences without undue experimentation, as only a single functional promoter sequence obtained from a BSV source is exemplified. With respect to the features of source and activity alone as defining allowable subject matter, the Examiner maintains that the features of source and activity alone are not sufficient to enable claims directed to polynucleotides that function as promoter sequences.

Claims 1, 3 and 6-19 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 1638

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed November 19, 2002.

Applicant's arguments filed February 27, 2003, have been fully considered but they are not persuasive.

Applicant argues that an analysis of the Written Description Guidelines and Training Examples, particularly Examples 9 and 14, would lead to the conclusion that Applicants were in possession of the claimed invention (reply page 9)

Applicant also argues that the designation of a sequence as a BSV sequence provides a limitation that forms part of the definition of the genus as claimed, and that sequences from other organisms fall outside of the claimed genus (reply page 9).

Applicant additionally argues that the claimed sequences having at least 95% identity to SEQ ID NO:2 do not have substantial variation, as all the variants must possess promoter activity and must be a BSV sequence, and that the single species disclosed is representative of the claimed genus because all members must have at least 95% structural identity with the reference sequence, and because Applicants have provided and exemplified a method for identifying all BSV polynucleotides at least 95% identical to SEQ ID NO:2 and having promoter function (reply pages 10-11).

Applicant further argues the disclosure of a single sequence is sufficient as a representative number of species because one skilled in the art would not expect substantial variation among the claimed hybridizing sequences, as the highly stringent conditions set forth in the claims would yield structurally similar DNAs, (reply pages 11-12).

With respect to the Written Description Guidelines and Training Examples, the Examiner maintains that Applicant's reference to Examples 9 and 14 is not germane to the instant rejection, because Examples 9 and 14 are directed to polynucleotides that encode proteins, which do not function in the same manner as do polynucleotides that are promoter sequences.

The Examiner also disagrees that the designation of a polynucleotide sequence as a BSV sequence would exclude from the claimed genus polynucleotide sequences from other organisms, because the genetic code is universal, such that all polynucleotides from all species of organisms utilize the same four nucleotides to codify their genetic information in the form of DNA. Absent further limitation, the designation "BSV" alone does not distinguish a polynucleotide obtained from BSV from a polynucleotide obtained from another source.

With respect to the claimed sequences having at least 95% identity to SEQ ID NO:2, or the claimed sequences that hybridize to SEQ ID NO:2 under highly stringent conditions, the Examiner maintains that because Applicant has not described any variant of SEQ ID NO:2, what would constitute "substantial variation" with respect to SEQ ID NO: 2 and its promoter function cannot be determined. The disclosure of a single sequence is not sufficient as a representative number of species in the instant case because Applicant has not described the structural features that would be shared by SEQ ID NO:2 and its functional variants.

Remarks

Claim 2 is allowed.

Claims 1-3 and 6-19 are deemed free of the prior art due to the failure of the prior art to teach or suggest an isolated nucleic acid sequence of SEQ ID NO:2, or isolated sequences with at least 95% similarity thereto.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 26, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

